IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	MDL NO. 1203
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9065

Bartle, J. May 10, 2013

Janice I. Phillips ("Ms. Phillips" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Jamie W. Oaks, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2007, claimant submitted a completed Green Form to the Trust signed by her attesting cardiologist, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed at least 322 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated November 30, 2006,[4] Dr. Evans

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3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Because claimant's November 30, 2006 echocardiogram was performed after the end of the Screening Period, claimant relied (continued...)

attested in Part II of claimant's Green Form that Ms. Phillips suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $532,711.[5]

In the report of claimant's November 30, 2006 echocardiogram, the reviewing cardiologist, R. Alex Case, M.D., F.A.C.C., observed that claimant had "an ejection fraction in the range of 60%."[6] An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In May, 2007, the Trust forwarded the claim for review by Noyan Gokce, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gokce concluded that there was no

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4. (...continued)
on an echocardiogram dated June 27, 2002 to establish her eligibility to receive Matrix Benefits. Given our resolution of this claim, we need not address any disputes relating to claimant's June 27, 2002 echocardiogram.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of the five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is claimant's ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

6. Claimant also submitted a report prepared in April, 2007 by Dr. Evans based on her November 30, 2006 echocardiogram. In this report, Dr. Evans stated, "The [left ventricular] ejection fraction is estimated to be 60%."

reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. Dr. Gokce explained, "[Left ventricular] systolic function appears normal with normal fractional shortening of 34%. Estimated [left ventricular ejection fraction] >60%."

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant submitted affidavits of Dr. Evans, Gregory R. Boxberger, M.D., F.A.C.C., Dan A. Francisco, M.D., F.A.C.C., and G. Whitney Reader, M.D., F.A.C.P., F.A.C.C. Each of these physicians observed that claimant's ejection fraction was near 60% and concluded that it was reasonable for the attesting physician to state that claimant had a reduced ejection fraction in the range of 50% to 60%. Claimant argued, therefore, that there was a reasonable medical basis for her claim because these Board Certified cardiologists independently agreed that she had a reduced ejection fraction. Claimant further asserted that the auditing cardiologist "apparently did not understand the

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

difference between his **personal opinion** ... and the 'reasonable medical basis' standard."

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On September 9, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7945 (Sept. 9, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 6, 2008, and claimant submitted a sur-reply on November 24, 2008. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D. F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The show cause record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she suffered from a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Phillips repeats the arguments she made in contest, namely, that the opinions of Dr. Evans, Dr. Boxberger, Dr. Reader, and Dr. Francisco provide a reasonable medical basis for the finding of a reduced ejection fraction. In addition, claimant contends that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's physicians and that of the auditing cardiologist, Dr. Gokce. According to claimant, there

is an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Rule, 16% when using the wall motion index, and 19% when using subjective visual assessment. Thus, Ms. Phillips contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that an ejection fraction is as high as 79%, a finding of an ejection fraction of 60% by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim because they merely disagree with, rather than rebut, Dr. Gokce's finding at audit that there is no reasonable medical basis for the attesting physician's representation of a reduced ejection fraction. The Trust also contends that inter-reader variability does not establish a reasonable medical basis for this claim because Dr. Gokce specifically determined that there was no reasonable medical basis for the attesting physician's finding.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Phillips had a reduced ejection fraction. Specifically, Dr. Vigilante determined,

> I reviewed the tape of the Claimant's echocardiogram of attestation.... The date was noted to be November 30, 2006.... This study was not performed in accordance with the usual medical standards. There were

> appropriate echocardiographic views including apical views. However, color doppler evaluation of the mitral regurgitant jet occurred only in the apical four chamber view and not apical two chamber view. In addition, there was an initial appropriate Nyquist limit of 61 cm per second at a depth of 17 cm in the apical four chamber view but this Nyquist limit was suddenly decreased to 50 cm per second resulting in inappropriate increased color gain. Despite this, this study was interpretable.
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> I was asked to evaluate the Claimants ejection fraction. Visually, the left ventricle was normal in size with excellent contractility. There were no regional wall motion abnormalities. It was obvious that there was normal contractility in the parasternal as well as apical views. I evaluated the cardiac cycles in the apical four and two chamber views in which the left ventricular endocardium could be identified. These cardiac cycles were digitized. I then determined the left ventricular end diastolic and end systolic areas by planimetering with calipers in both the apical two and four chamber views. I determined the ejection fraction by Simpson's Method. The left ventricular ejection fraction was 68%. This ejection fraction never came close to approaching 60%.
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> ... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question F.8. That is, the echocardiogram of November 30, 2006 demonstrated an ejection fraction of 68%. An echocardiographer could not reasonably [have] concluded that the ejection fraction was in the range of 50%-60% when making appropriate quantitative measurements even taking into account the issue of inter-reader variability.

After reviewing the entire Show Cause Record, we find that claimant's arguments are without merit. As an initial

matter, claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor. Claimant does not rebut Dr. Gokce's determination that claimant's "[left ventricular] systolic function appears normal with normal fractional shortening of 34%. Estimated [left ventricular ejection fraction] >60%."[9] Nor does claimant challenge Dr. Vigilante's conclusion that claimant's "left ventricle was normal in size with excellent contractility" and that claimant's ejection fraction was 68%.[10] Neither claimant nor her experts identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor.[11] Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Phillips had a reduced ejection fraction is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement

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9. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

11. Thus, we reject claimant's argument that these opinions provide a reasonable medical basis for her claim.

Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the claimant does not adequately refute the auditing cardiologist's determination that Ms. Phillips had an ejection fraction greater than 60% and the Technical Advisor concluded that claimant's ejection fraction was 68%. Adopting claimant's argument that inter-reader variability expands the range of a reduced ejection fraction by as much as ±19% would allow a claimant to recover benefits with an ejection fraction as high as 79%. This result would render meaningless this critical provision of the Settlement Agreement.[12]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we affirm the Trust's denial of the claim of Ms. Phillips for Matrix Benefits and the related derivative claim submitted by her spouse.

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12. Moreover, the Technical Advisor specifically took into account the concept of inter-reader variability as reflected in his statement that, "An echocardiographer could not reasonably [have] concluded that the ejection fraction was in the range of 50%-60% when making appropriate quantitative measurements even taking into account the issue of inter-reader variability."